

REMARKS

Reconsideration and allowance of this application in view of the foregoing amendments and following remarks are respectfully requested.

Claims 1, 4, 7, 20, 23 and 26 were rejected under 35 U.S.C. §102 as anticipated by Arkangel, Goodfellow et al., Cloutier or Murray et al. Independent claims 1, 4, 20 and 23 have been amended to provide Applicants with the broad scope of protection to which they believe themselves to be entitled and to better define their claimed invention over such cited prior art. More specifically, these independent claims have been amended to recite that Applicants' bearing insert means slidably engages the platform means "for sliding movement relative thereto during joint articulation" and to recite means for constraining motion of the bearing insert means "during joint articulation to a predetermined path" relative to the platform means. Such novel structure, and by way of example with regard to Applicants' knee joint embodiment, allows the needed anterior-posterior and axial rotation motions of the knee while substantially reducing incongruency of contact, and hence reduces wear.

With regard to the disclosures of Arkangel and Murray, it will be noted that neither the plateau member 20 of Arkangel nor the tibial component 14 of Murray have any sliding movement relative to their respective tibial platforms during joint articulation; to the contrary, while such components slidably engage their respective tibial components during assembly, they do not move at all during joint articulation, rather they are fixed and not movable during joint articulation. Hence, the prostheses of Arkangel and Murray neither disclose Applicants' claimed structure nor provide Applicants' novel functions.

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With regard to Goodfellow et al. and Cloutier, it is noted that neither the meniscal component 30 of Goodfellow et al. nor the removable condylar bearing members 7 and 9 of Cloutier include any "means for constraining motion of the bearing insert means during joint articulation to a predetermined path relative to the platform means." To the contrary, it will be noted that the meniscal component 30 of Goodfellow et al., embodiment of FIGS. 1 and 2, is unconstrained and can slide freely with respect to tibial surface 22 in all directions, and that in the embodiment of FIG. 3, the meniscal component 30 has relative sliding movement which can occur in all directions of the surfaces 22 and 33 up to the limits imposed by abutment of the projection with the recessed side wall (see Col. 6, lines 14-17); hence in neither embodiment is the Goodfellow et al. meniscal component 30 constrained during joint articulation to motion along a "predetermined path." Similarly, it will be noted that the removable condylar bearing members 7 and 9 of Cloutier are free to move in all directions within the respective trays 41 and 43 without any preferential direction of motion; this can be seen most readily from FIGS. 5 and 6 which show medial-lateral clearances equal to the anterior-posterior clearances between such components and their respective trays. Hence, the removable condylar bearing members 7 and 9 of Cloutier are not constrained during joint articulation to motion along a "predetermined path."

Applicants' invention, defined by the amended independent claims, represents an advance over Goodfellow et al. and Cloutier in that such claimed invention provides desired constraint of unneeded and undesirable motions of the bearing

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insert means relative to the platform means thereby improving stability of the bearing insert means and hence stability of the joint. For example, Applicants' claimed invention when embodied as a knee prosthetic joint, constrains medial-lateral motion of the bearing insert means relative to the tibial platform means while still allowing the bearing insert means to provide unrestricted anterior-posterior and axial rotation within normal limits imposed by soft tissue. Goodfellow et al.'s teaching of the slidable meniscal component 30 is to provide a knee prosthesis permitting normal knee motions while reducing contact stresses to provide improved wear characteristics. In the embodiment of FIGS. 1 and 2, the slidable meniscal component 30 provides no medial-lateral stability and while such meniscal component in the embodiment of FIG. 3 may provide some medial-lateral stability, it does so by paying the price of severely and highly undesirable restricted anterior-posterior motion due to the mushroom projection 25. Further, it will be noted that the disadvantages of the Goodfellow et al. prosthesis are taught in detail in Applicants' specification, page 5, line 29-p. 8, line 23, and illustrated in Applicants' FIGS. 1A-6B, and the manner in which Applicants' invention overcomes these disadvantages is also set forth in detail in Applicants' specification, page 32, line 27 et seq., and shown in the drawings. Similarly, Cloutier, while apparently providing some medial-lateral stability of his removable condylar bearing members 7 and 9 also has severely and undesirably restricted anterior-posterior motion of such members.

Accordingly, it is respectfully submitted that amended claims 1, 4, 20 and 23 are not anticipated by such cited references and are allowable thereover under 35 U.S.C. §102.

With regard to dependent claims 7 and 26, dependent respectively on amended independent claims 1 and 23, it is submitted that such dependent claims are allowable under 35 U.S.C. §102 over the cited references for the same reasons set forth distinguishing the independent claims. Further, it is respectfully submitted that such dependent claims as amended to recite that the retention means are for preventing dislocation of the bearing insert means from the tibial platform means, "during the normal range of knee motion" further define patentable subject matter over the cited references under 35 U.S.C. §102 and the allowance of dependent claims 7 and 26 is respectfully solicited.

Referring now to paragraph 2 of the outstanding Office Action and the rejection of the claims referred to therein, it is respectfully submitted that dependent claims 2, 3, 5, 6, 21, 22, 24 and 25 define patentable subject matter in view of the foregoing remarks patentably distinguishing the independent claims upon which they respectively depend. Further, it is respectfully submitted that such dependent claims and independent claims 9 and 28 define patentable subject matter under 35 U.S.C. §103 in view of the combinations of the basic references cited in paragraph 1 of the outstanding Office Action and the secondary references cited in paragraph 2 of the outstanding Office Action. More specifically, it is submitted that it is not obvious to

combine Goodfellow et al. or Cloutier with either Helfet or Waugh et al. because Goodfellow et al. already provides axial rotation and therefore has no need for a curved or circular curved track to provide rotation; similarly, in the case of Cloutier, Cloutier needs no curved or circular track to provide axial rotation because Cloutier is an incongruent type of contact prosthesis (note FIG. 7) and hence already provides axial rotation. Also, Murray already provides axial rotation and therefore neither needs a curved or circular curved track for axial rotation. Combining Arkangel with either Helfet or Waugh et al. is not well founded since inserting the fixed plateau member 20 of Arkangel in a curved track would fail to provide any added rotation. Still more specifically, Waugh et al. and Helfet are attempting to obtain axial rotation with less congruency and since neither of their disclosures include any bearing insert means, their disclosures, per se, are not pertinent to the subject rejected claims. Applicants' invention, on the other hand, which constrains medial-lateral motion to provide medial-lateral stability does require a curved track, e.g. a circular curved track, in order to provide axial rotation and hence it is respectfully submitted that the subject claims reciting the curved track and circular curved track define patentable subject matter over the combined references as set forth in paragraph 2 of the outstanding Office Action. Accordingly, it is submitted that the subject claims, as amended and as dependent on the respective amended independent claims, define patentable subject matter under 35 U.S.C. §103 in view of the combination of cited references.

Referring now to paragraph 3 of the outstanding Office Action, it is respectfully submitted that claims 8 and 27

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define patentable subject matter for the foregoing remarks patentably distinguishing the dependent claims on which they directly depend and the independent claims upon which they indirectly depend. Further, it is respectfully submitted that no teaching is to be found in any of the cited references, alone or in combination, of substituting a dove-tail joint with the mating arrangements between the bearing insert and tibial component and tibial insert disclosed in Murray et al. or Goodfellow et al. It is only Applicants that disclose and claim such novel structure, and accordingly it is respectfully submitted that claims 8 and 27, as amended to better define Applicants' invention, define non-obvious subject matter over the cited references under 35 U.S.C. §103 and their allowance is respectfully solicited.

Independent claims 10 and 29 have been amended to better define Applicants' invention and to further provide Applicants with the scope of protection to which they are entitled by now reciting that the bearing insert means slidably engage the platform means, "for sliding movement relative thereto during joint articulation," and to recite means for constraining motion of the bearing insert means, "during joint articulation to a predetermined path" relative to the platform means. As noted above with regard to the remarks patentably distinguishing independent claims 1, 4, 20 and 23 over Goodfellow et al. and Cloutier, such structure is not present in either Goodfellow et al. or Cloutier. Accordingly, it is respectfully submitted that claims 10 and 29, as amended, are not anticipated by either Goodfellow et al. or Cloutier under 35 U.S.C. §102 and their allowance is respectfully requested.

Dependent claims 11, 12, 30 and 31 have been amended to further define Applicants' invention and it is respectfully submitted that such dependent claims are allowable for the foregoing remarks patentably distinguishing the independent claims, claims 10 and 29, upon which they directly and indirectly depend. Further, it is submitted that such claims, particularly as amended, define patentable subject matter under 35 U.S.C. §103 for the same preceding remarks patentably distinguishing the claims rejected in paragraph 2 of the outstanding Office Action over the combination of either Goodfellow et al. or Cloutier in view of Waugh et al. or Helfet. Thus, it is respectfully submitted that claims 11, 12, 30 and 31, particularly as amended, define patentable subject matter over the combination of cited references under 35 U.S.C. §103.

With regard to the rejection of dependent claims 13 and 32, in paragraph 6 of the outstanding Office Action, it is respectfully submitted that such claims define patentable subject matter for the foregoing remarks patentably distinguishing independent claims 10 and 29 upon which such claims depend. Accordingly, it is submitted that independent claims 13 and 32, dependent upon their respective independent claims, define patentable subject matter under 35 U.S.C. §102.

Referring now to claims 18 and 37, which recite Applicants' novel provision of slight incongruency, it is submitted that these claims define patentable subject matter for the foregoing remarks distinguishing the claims upon which they depend. Further, it will be noted that Goodfellow et al. needs no incongruency in order to permit axial rotation or anterior-posterior motion and hence there is no need to combine Goodfellow et al. with either Helfet or Walker et al. Cloutier

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is already incongruent (note FIG. 7) so therefore there is no need to combine either Walker et al. or Upshaw et al. with Cloutier to provide incongruency whether slight or otherwise. Applicants provide slight incongruency to obtain desired anterior-posterior motion and axial rotation while still providing substantial congruent contact to reduce wear. The primary distinction between Applicants' invention and the prior art references is that Applicants' incongruency is very slight and is coupled in a novel manner with stable bearing elements to allow desired anterior-posterior motion and axial rotation. Further, it is respectfully submitted that the Examiner's contention that a slight incongruency is an obvious modification of the primary references is not well founded in that the secondary references show major incongruency as will be revealed by a close examination of their respective figures. Accordingly, it is submitted that claims 18 and 37 define non-obvious subject matter under 35 U.S.C. §103 in view of the combination of cited references.

Referring now to paragraph 10 of the outstanding Office Action, it is respectfully submitted that claim 39 as it is dependent on claims 20-27 and 36 is patentable under 35 U.S.C. §103 for the foregoing reasons patentably distinguishing the claims upon which claim 39 depends. Further, it is respectfully submitted that the further teaching of Waugh ('864) merely teaches that both ankle prostheses, as represented by the disclosure of Waugh, and knee prostheses, as represented by the disclosure of Waugh et al., are known to the prior art. The structural elements recited in claim 39, as dependent variously on claims 20-27 and 36, are not to be found in such references either alone or in combination and hence the allowance of claim 39 is respectfully solicited.

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Referring now to the rejection of paragraph 11 of the outstanding Office Action, it is respectfully submitted that claims 20-26 are not anticipated by Gristina under 35 U.S.C. §102 particularly as independent claims 20 and 23 are amended. It will be noted that independent claims 20 and 23, as amended, recite that Applicants' bearing insert means slidably engages the bearing surface of the platform means, "for sliding movement relative thereto during joint articulation" and that the prosthetic joint defined includes means for constraining motion of the bearing insert means, "during joint articulation to a predetermined path" relative to the platform means. Such structure is not to be found in Gristina and it is respectfully submitted that such independent claims define patentable subject matter under 35 U.S.C. §102 over Gristina. Further, it is respectfully submitted that dependent claims 21, 22, 24, 25 and 26 are patentable over Gristina for the same reasons distinguishing the independent claims from which they depend and further because the further recitations included in such dependent claims are not to be found in Gristina. Accordingly, it is submitted that such claims define patentable subject matter over Gristina under 35 U.S.C. §102.

Referring now to newly added dependent claims 1A, 4A, 9A, 10A, 20A, 23A, 28A and 29A, it is respectfully submitted that the track surface means and track surface following means recited by such claims are neither taught nor suggested by the cited prior art references either alone or in combination. Accordingly, it is respectfully submitted that such newly added claims define patentable subject matter under 35 U.S.C. §102 and 35 U.S.C. §103.

It is respectfully submitted that Applicants' invention is a major advance in the prosthetic joint art and that Applicants' invention includes numerous patentable features. Accordingly, it is respectfully submitted that Applicants are entitled to claim their invention by varying language to provide the scope of protection to which they are fairly entitled vis-a-vis the prior art. Accordingly, claims 40 through 50 have been added to provide Applicants with the further scope of protection to which they are entitled. It is respectfully submitted that such newly added claims are properly examinable with the elected invention and require no different search of the prior art with respect to the elected invention. Still further, it is respectfully submitted that the invention defined by such newly added claims is fully disclosed in the originally filed specification and accompanying drawings and that they do not include any new matter. The prosthetic joints defined by such newly added claims have been compared vis-a-vis the disclosures of the cited prior art references, alone and in combination, and it is respectfully submitted that such newly added claims define patentable subject matter over such cited references, alone or in combination, under 35 U.S.C. §102 and 35 U.S.C. §103. Their allowance is accordingly respectfully solicited.

Referring now to the amendment of the specification, the specification has been amended where indicated to change "planform" to --form in plan view-- and it is submitted that it is proper and not an addition of any new matter in that the amended language merely describes narratively what Applicants intended by "planform" which they believed to be a properly descriptive term.

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A European Search Report has been received by Applicants in connection with European Patent Application No. 80103598.1 corresponding to the instant application. A copy of such European Search Report is attached hereto in further fulfillment of Applicants' duty to disclose information which is, or may be, material to the examination of this application. The most pertinent reference cited in the European Search Report is British Patent Specification No. 1,567,007, published 8 May 1980, a copy enclosed for convenience. Since such British specification was not published more than one year prior to Applicants' filing date, it is not a reference against Applicants' invention under 35 U.S.C. §102 and since it was not published prior to Applicants' filing date, it is not a reference against Applicants' invention under 35 U.S.C. §103.

Reconsideration and allowance of this application in view of the claim amendments and the foregoing distinguishing remarks are respectfully requested.

Respectfully submitted,

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